Laser-Assisted In Situ Keratomileusis for Patients With Dry Eye

Ikuko Toda, MD; Naoko Asano-Kato, MD; Yoshiko Hori-Komai, MD; Kazuo Tsubota, MD

Objective: To evaluate the efficacy and safety of laser-assisted in situ keratomileusis (LASIK) in patients with preoperative dry eye.

Methods: We divided the 543 eyes that underwent LASIK into the following 3 groups: eyes with definite dry eye (DE group), with probable dry eye (PDE group), and without dry eye (NDE group). We evaluated visual outcome, dry-eye status, and complications.

Outcome Measures: We compared uncorrected and best-corrected visual acuity, manifest refraction, symptoms, tear function, ocular surface abnormality, complications, corneal sensitivity, endothelial cell count, and patient satisfaction among the groups.

Results: We found no significant differences among the groups in uncorrected and best-corrected visual acuity, manifest refraction, and patient satisfaction. A dry-eye symptom, dryness, was more severe in the DE than the NDE group after LASIK. The mean results of the Schirmer test with anesthesia and tear breakup times were significantly lower and the fluorescein score was higher in the DE than the NDE groups after LASIK. We found no differences in the incidence of complications among the groups. Corneal sensitivity was recovered within 6 months after LASIK in the DE and PDE groups and within 3 months in the NDE group.

Conclusions: The efficacy and safety of LASIK were not affected by preexisting dry eye. However, preexisting dry eye is a risk factor for severe postoperative dry eye with lower tear function, more vital staining of the ocular surface, and more severe symptoms.

Arch Ophthalmol. 2002;120:1024-1028
PATIENTS AND METHODS

We enrolled 543 eyes of 290 consecutive patients (mean age, 33.1 years) who underwent LASIK from January 1, 1998, through March 31, 2000, at the Minamiaoyama Eye Clinic, Tokyo, Japan, in this study. These eyes were divided into the following 3 groups on the basis of preoperative dry-eye status: eyes with definite dry eye (DE group; 111 patients and 168 eyes), with probable dry eye (PDE group; 153 patients and 300 eyes), and without dry eye (NDE group; 49 patients and 75 eyes). Dry eye was diagnosed according to the modified criteria established by the Japanese Dry Eye Association. The subcriteria consisted of results of a Schirmer test with anesthesia of no greater than 5 mm, and/or tear breakup time (BUT) of no greater than 5 seconds, and a fluorescein score of at least 1 and/or a rose brown score of at least 3. Briefly, patients who satisfied both subcriteria were diagnosed as having DE; those who satisfied 1 of 2 subcriteria, PDE. The mean ± SD preoperative refraction in spherical equivalent was −7.24 ± 3.09 diopters (D) in the DE group, −6.82 ± 2.85 D in the PDE group, and −6.5 ± 2.94 D in the NDE group.

For the surgical procedure, a corneal flap was created with a microkeratome (LSK One; Moria, Antony, France; or MK-2000; NIDEK Co, Ltd, Gamagori, Japan), and laser ablation was performed using an excimer laser (Apex-plus; Summit Technology, Walnut Creek, Calif; or EC-3000; NIDEK Co, Ltd). Hyaluronate sodium (Hyanein; Santen Pharmaceutical Co, Ltd, Osaka, Japan) and balanced salt solution (BSS Plus; Alcon Laboratories, Ft Worth, Tex) were frequently applied intraoperatively to prevent dehydration of the ocular surface. Immediately after surgery, high viscous methylcellulose (Lacrivisc; Alcon, Hunenberg, Switzerland) was instilled in the eye and patients were asked to close their eyes and rest for 15 minutes. Low-dose corticosteroids (0.1% fluorometholone [Flumetholon; Santen Pharmaceutical Co, Ltd]), antibiotics (ofloxacin [Tarivid; Santen Pharmaceutical Co, Ltd]), and 0.3% hyaluronate sodium eye-drops were prescribed 5 times a day. Eyedrop therapy was discontinued at 1 week postoperatively. Hyaluronate sodium eye-drops remain on the ocular surface longer than isotonic sodium chloride–based artificial tears and manifest the symptoms and ocular surface damage caused by post-LASIK dry eye.

To evaluate the efficacy of the LASIK correction, uncorrected (UCVA) and best-corrected visual acuity (BCVA) and manifest refraction in the spherical equivalent were examined at 1, 3, and 6 months and 1 year after LASIK.

mised tear function and ocular surface for at least 1 month after surgery. Tear function and dry-eye symptoms improve within several postoperative months in most cases; however, some patients still have dry eye 1 year after undergoing LASIK. Although the mechanisms for post-LASIK dry eye are unclear, more severe post-LASIK dry eye may develop in patients with preoperative dry eye for longer periods compared with subjects without preoperative dry eye. The purpose of this study was to investigate whether (1) preoperative dry eye may affect the visual outcome and incidence of complications after LASIK, and (2) preoperative dry eye is a risk factor for severe postoperative dry eye.

For the dry-eye examination, we assessed dry-eye symptoms and performed a Schirmer test with anesthesia, measurement of tear BUT, and fluorescein and rose bengal staining of the ocular surface. For subjective symptoms of dry eye, dryness was graded by the patients according to the following scale: 0 indicates none; 1, mild; 2, moderate; 3, strong; and 4, very strong. The Schirmer test with anesthesia was performed 5 minutes after instilling 10 µL of 0.5% fluorescein sodium and 0.4% benoxinate hydrochloride into the conjunctival sac. The Schirmer strip was placed for another 5 minutes, and the length of the wet portion was measured. Vital staining of the ocular surface was performed by instillation of 2 µL of preservative-free mixed-dye solution (1% rose bengal and 1% fluorescein) into the conjunctival sac. Fluorescein staining results were graded from 0 to 3 for the upper, middle, and lower thirds of the cornea. Rose bengal staining results were graded from 0 to 3 for the temporal conjunctiva, cornea, and nasal conjunctiva. Staining was graded by the extent as 0 for negative; 1, scattered minute; 2, moderate spotty; and 3, diffuse blotchy. The tear BUT was measured as the number of seconds between the last complete blink and the first disturbance of the precorneal tear film.

The safety of LASIK was evaluated by incidence of intraoperative (epithelial defect, bleeding, and flap repositioning) and postoperative (recurrent erosion, diffuse lamellar keratitis, microstriae, and epithelial ingrowth) complications, corneal sensitivity, loss of BCVA, and endothelial cell count. Corneal sensitivity was measured with an anesthesiometer (Chocet-Bonnet; Luneau Ophthalmologie, Chartres, France) consisting of a nylon filament 60.0 mm long and 0.12 mm in diameter. Patients were asked to look straight ahead and to indicate when they believed that the top of the nylon filament touched the cornea. The measurement was started at 60.0 mm, and the length of the filament was decreased by 5.0-mm increments to increase its rigidity. The corneal sensitivity was defined as the length of the filament that produced a first positive response. We photographed the corneal endothelium using a specular microscope (Konan Medical, Inc, Tokyo), and calculated mean cell density.

We surveyed overall patient satisfaction with the outcome of LASIK, using a grade of 1 for very satisfied; 2, satisfied as expected; 3, not very satisfied; and 4, regretted undergoing LASIK.

We performed statistical analysis by means of the t test, Wilcoxon rank sum test, or Kruskal-Wallis test. Values of $P<.05$ were considered statistically significant.

RESULTS

VISUAL OUTCOME

We found no significant differences among the DE, PDE, and NDE groups in UCVA and BCVA, except at 1 month, when the UCVA was better in the NDE than in the DE group ($P = .03$). Average postoperative manifest refraction was within ±0.5 D in all groups at all follow-ups. Manifest refractive deviation due to emmetropia was slightly larger in the DE than in the NDE group at 3 months (−0.25±0.76 vs 0.01±0.55 D; $P = .01$), but we found no differences among the groups at other follow-up points.
Dry-eye symptoms before and after laser-assisted in situ keratomileusis (LASIK) in the groups with definite (DE) and probable dry eye (PDE) and without dry eye (NDE). Asterisk indicates \( P < .01 \); dagger, \( P < .05 \); and error bars, SD.

**Figure 1.** Dry-eye symptoms before and after LASIK.

**Figure 2.** A). The rose bengal score was lower in the DE and PDE groups compared with the NDE group. The examination data determined by results of the Schirmer test, tear BUT, and rose bengal and fluorescein stainings were more compromised after LASIK in the DE group compared with the NDE group. The examination data of patients in the PDE group yielded values that were between those of the DE and NDE groups. A typical dry-eye condition of patients in the PDE group yielded values that were between those of the DE and NDE groups. The rose bengal score was higher in the DE and PDE groups than in the NDE group preoperatively and at 3 months after LASIK (Figure 3A). The rose bengal score was higher in the DE and PDE groups than in the NDE group preoperatively and at 3 months after LASIK (Figure 3B).

**Figure 3.** A). The rose bengal score was lower in the DE and PDE groups compared with the NDE group. The examination data determined by results of the Schirmer test, tear BUT, and rose bengal and fluorescein stainings were more compromised after LASIK in the DE group compared with the NDE group. The examination data of patients in the PDE group yielded values that were between those of the DE and NDE groups. A typical dry-eye condition of patients in the PDE group yielded values that were between those of the DE and NDE groups. The rose bengal score was higher in the DE and PDE groups than in the NDE group preoperatively and at 3 months after LASIK (Figure 3B).

**Figure 4.** The efficacy of LASIK, determined by means of postoperative UCVA, BCVA, and manifest refraction, was almost comparable in the 3 groups. However, UCVA at 1 month and manifest refraction at 3 months were better in the NDE than in the DE group. We speculate that these differences were due to slight differences in the amount of correction between the groups. The mean refractive correction was \(-7.20\) D in the DE group and \(-6.47\) D in the NDE group (\(P = .07\)).

**SAFETY**

Intraoperative epithelial defect occurred in 4 eyes in the NDE group (\(P = .2\)). Fifty-eight eyes (34.5%) in the DE, 78 (26.0%) in the PDE, and 20 (26.7%) in the NDE groups had bleeding from the pannus (\(P = .5\)). Flap repositioning was performed immediately after surgery owing to flap folds or dislocated flaps in 4 eyes (2.4%) in the DE, 11 (3.7%) in the PDE, and 2 (2.7%) in the NDE groups (\(P = .7\)). We found no significant differences in the incidence of postoperative complications, ie, epithelial ingrowth of 6 eyes (2.0%) in the PDE group, diffuse lamellar keratitis of 1 eye (0.6%) in the DE group, microstriae of 5 eyes (3.0%) in the DE and 8 eyes (2.7%) in PDE groups, and no recurrent corneal erosion.

Loss of BCVA of more than 2 lines was observed in 2 eyes (1.2%) in the DE, 7 (2.3%) in the PDE, and 1 (1.3%) in the NDE groups (\(P = .4\)) at 1 year after LASIK.

Conical sensitivity recovered to preoperative levels within 6 months after LASIK in the DE and PDE groups and within 3 months in the NDE group (Figure 4). However, no statistical difference was found among the groups at any follow-ups. Endothelial cell count was unchanged after LASIK in all groups.

**PATIENT SATISFACTION**

We found no significant differences in satisfaction among the groups at 3 and 6 months and 1 year after surgery.
lead to postoperative uncomfortable symptoms caused by dry eye and/or LNE.

Epithelial problems during or after LASIK surgery were of biggest concern in patients with preexisting dry eye. Although we treated some patients who had severe ocular surface damage caused by dry eye with punctal plugs before surgery, most of our patients underwent LASIK without any dry-eye pretreatment except for artificial tears. Epithelial defect, recurrent erosion, and epithelial ingrowth did not preferentially occur in patients with preoperative dry eye. Incidence of other problems, such as flap dislocation, flap folds, microstriae, and diffuse lamellar keratitis was not increased in patients with dry eye. For long-term complications, we found no statistically significant difference in the loss of BCVA between the groups. However, recovery of corneal sensitivity was significantly slower in patients with dry eye. This finding may be explained by dysfunction of tear dynamics in dry eye, because corneal sensitivity is sometimes decreased in these patients. Alternatively, delayed recovery of corneal nerves may be responsible for tear deficiency in these patients. The other possibility is that the difference may be attributable to the amount of corneal tissue ablation, which was increased in the DE group in this study. Kim and Kim reported that greater reduction of corneal sensitivity was observed in cases with deeper ablation.
CONCLUSIONS

Our results indicate that the efficacy and safety of LASIK were not affected by preexisting dry-eye status. With the proper ocular surface management, patients with dry eye can be good candidates for LASIK. However, our results also suggest that preexisting dry eye is a risk factor for severe postoperative dry eye with lower tear function, more vital staining of the ocular surface, and more severe dry-eye symptoms until 1 year after LASIK. Patients with dry eye who expect complete resolution of their symptoms after LASIK with removal of contact lenses should be warned that their dry-eye symptoms may persist after LASIK. We have recently found that some patients complain of dry-eye symptoms for more than 1 year after LASIK. The pathogenesis and risk factors of such symptoms are now under investigation.

Submitted for publication October 23, 2001; final revision received March 19, 2002; accepted April 16, 2002.

We thank Chikako Sakai of the Minamiaoyama Eye Clinic for her assistance in statistical analyses.

Corresponding author and reprints: Ikuko Toda, MD, Minamiaoyama Eye Clinic, 2-27-25 Minamiaoyama, Minato-ku, Tokyo 107-0062, Japan (e-mail: ikuko@tka.att.ne.jp).

REFERENCES


Notice to the Authors of Reports From Clinical Trials

The Journal of the American Medical Association (JAMA) and the Archives of Ophthalmology function as an editorial consortium. With one submission and one set of reviews, your clinical trial manuscript will be considered for publication in both JAMA and the Archives of Ophthalmology.

Submit your paper to the journal of your choice according to the appropriate “Instructions for Authors” and the following guidelines will apply:

1. If your manuscript is accepted by JAMA, it will be considered for an editorial or commentary in JAMA. Your abstract will also be published in the Archives of Ophthalmology with a commentary or editorial.
2. If your manuscript is accepted by the Archives of Ophthalmology, it will be considered for an editorial or commentary in the Archives of Ophthalmology. Your abstract will also be considered for publication in JAMA.